Remarks

Claims 53, 55-58, 60, 64, 66-68 and 74-82 are pending. The claims of the present invention contain the same subject matter as the claims presently allowed in Europe.

35 U.S.C. 103(a) Rejection

Claim 53, 56, 58, 60, 66-68 and 74-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bodmer et al. (U.S. Patent No. 5,538,739) in view of GB 2,145,422 and Reiners et al. (U.S. Patent No. 4,879,402). The Examples alleges that it would have been obvious to one of ordinary skill in the art to purify the polymer of Bodmer et al. using activated charcoal in view of the teaching in GB '422 to use a conventional purification technique and further in view of the teaching in Reiners et al. that, in a method of making a polymer using Sn octoate, the beneficial effect of purification to clarity is achieved using activated charcoal. Applicants respectfully disagree.

The present invention relates to pharmaceutical compositions comprising a polylactide polymer and a hydrophilic or lipophilic drug. The polylactide polymer is in a purified state and comprises an ester of a polyol containing at least three hydroxyl groups and is off-white to white in color. The polylactide polymer contains one or more metals in cationic form wherein the metals have a concentration up to 10ppm.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Bodmer et al. describe microparticles comprising polypeptides. Bodmer et al. do not teach or suggest all the claim limitations recited in the present claims.

The Examiner mentions that GB'422 teaches a method of making the polymer wherein the catalyst Sn octoate is preferred. Purification in the conventional manner is disclosed as meaning hydrolysis with HCl, see e.g. example 1. Purification to clarity does

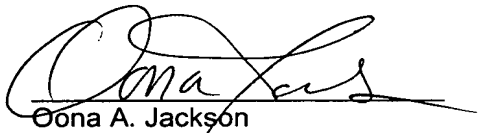
not mean that tin is removed from the clarified end product as tin has little to no impact on the color of the end product.

U.S. Patent No. 4,879,402 is a purification process for polymers that are used for dental materials. According to the Examiner, Examples 4 and 5 of U.S. Patent No. 4,879,402 are teaching purification to remove colored impurities via filtration through silica gel or active charcoal in order to obtain colorless liquids. The brown color is mostly due to the impurities coming from the preparation process of the polymer, e.g. degradation products. Said degradation products are removed with silica gel or active charcoal. Examples 4 and 5 are silent about the removal of tin and about the tin content of the end product. Therefore, there is no teaching about the efficient removal of tin using active charcoal.

GB'422 was filed before U.S. Patent No. 4,879,402, therefore it does not refer to any of the purification processes of U.S. Patent No. 4,879,402. Moreover, U.S. Patent No. 4,879,402 does not refer to GB'422 either, thus the person skilled in the art cannot find any incentive to apply the purification of Examples 4 and 5 of U.S. Patent No. 4,879,402 to remove tin. Therefore a person of ordinary skill in the art would not be motivated by the prior art references to combine the two documents nor to use active charcoal rather than silica gel to remove tin, as the color of the end product is due to degradation products and not to tin.

Entry of this Response is respectfully requested.

Respectfully submitted,



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